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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,221	07/15/2003	Gary A. Koppel	22064-71990	8706

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BARNES & THORNBURG LLP
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,221	KOPPEL, GARY A.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1,7-10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-6 and 11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are presented for examination.

Claims 1, 7-10 and 12-17 are withdrawn pursuant to 37 C.F.R. 1.142(b) as being directed to non-elected subject matter.

Applicant's response filed January 22, 2007 to the requirement for restriction dated September 22, 2006 has been received and entered into the present application. An election of species of cognitive disorder, clavulanic acid compound and P-glycoprotein efflux pump inhibitor was inadvertently omitted from the previous restriction requirement. Accordingly, the requirement for election of species is set forth below and will direct further prosecution of the elected invention of claims 2-6 and linking claim 11 (i.e., method for treating cognitive disorders).

Requirement for Election/Restrictions

This application contains claims directed to the following patentably distinct species of: (1) cognitive disorders (see, e.g., claims 3-4), (2) clavulanic acid compound(s) and (3) P-glycoprotein efflux pump inhibitor (see, e.g., claims 5-6).

The species are independent and/or distinct for the following reasons:

Regarding the species of cognitive disorders, the species are independent or distinct because such disorders for which the claimed clavulanic acid must be therapeutically effective are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of active agent, frequency of treatment, etc.) and patient population such that a comprehensive search for the claimed compound in an amount effective to treat, for example, dementia *per se*, would not necessarily anticipate, suggest or render obvious the administration of the same or different compound in an amount effective to treat an etiologically and pathophysiologically distinct disorder, such as Alzheimer's disease. While it is noted that there may be some overlap between the disorder of Alzheimer's disease and the conditions of dementia and/or amnesia, it remains that the

disorders of dementia *per se* and amnesia *per se* can occur in the absence of Alzheimer's disease and, thus, a comprehensive search of the patent and non-patent literature for dementia and/or amnesia *per se* would not necessarily result in a comprehensive search for Alzheimer's disease. Furthermore, the known complexity of the condition of Alzheimer's disease is further evidence that a comprehensive search for a particular agent to treat dementia and/or amnesia would not necessarily anticipate or render obvious to use of the same for Alzheimer's disease. Notwithstanding that Applicant may have established an underlying commonality to this genus of cognitive disorders, namely that each may be treated via clavulanic acid, it remains that the art does not necessarily recognize such a shared characteristic as being common to the entire genus of diseases encompassed by the claim, nor does the art necessarily recognize each as amenable to the same type of pharmacologic therapy. Each is considered independent or distinct from the others because the patient populations, dosage amounts and therapeutic protocol for treating each single condition are each unique to the type of disorder being treated such that a comprehensive search for the claimed compound in an amount effective for the treatment of a particular disease in the prior art would not necessarily encompass a comprehensive search of the patent or non-patent literature for the claimed compound in an amount effective for the treatment of any one or more other diseases.

Regarding the species of clavulanic acid compounds and P-glycoprotein efflux pump inhibitors, the species are independent or distinct because the breadth of agents are structurally and chemically distinct from any one other agent encompassed by the presently claimed genera of clavulanic acid compounds and P-glycoprotein efflux pump inhibitors such that a comprehensive search of the patent and non-patent literature for any one such compound(s) would not necessarily result in a comprehensive search of any one or more of the other agents encompassed by the claims. Additionally, in consideration of the number and significant chemical, functional and structural variability of compounds actually claimed by such a genus, the disparate nature and breadth of agents encompassed by this genus precludes a quality examination on the merits, not only because a burdensome search would be required for the

entire scope of the claim(s), but also because the consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112, would be unduly onerous. Further, though Applicant has recognized a common functionality to the claimed compounds, e.g., that they are capable of treating cognitive disorders, it remains that the art does not necessarily recognize such a function as being shared by the entire claimed genera of agents and, as a result, does not necessarily recognize their equivalency or interchangeability.

Applicant is required, in reply to this action, to elect:

(A) a **single disclosed specie** of cognitive disorder specifically claimed (see, e.g., claims 3-4) **or** a generic cognitive disorder not specifically claimed;

(B) a **single disclosed specie** of clavulanic acid compound specifically claimed, i.e., clavulanic acid or salt(s) or clavulanic acid or an active ester form of clavulanic acid that is hydrolyzed *in vivo* to clavulanic acid, (see, e.g., claim 11) **or** a generic clavulanic acid compound not specifically claimed; and

(C) a **single disclosed specie** of P-glycoprotein efflux pump inhibitor.

If Applicant elects a salt of clavulanic acid, then Applicant must further elect a specific species of salt of clavulanic acid (e.g., sodium salt of clavulanic acid, etc.)

If Applicant elects an active ester form of clavulanic acid that is hydrolyzed *in vivo* to clavulanic acid, then Applicant must further elect specific species of active ester form of clavulanic acid that is hydrolyzed *in vivo* to clavulanic acid. **Applicant is further required to provide a structural depiction of such a compound, if so elected as the species for examination on the merits.**

Applicant is cautioned that the election of a particular specie of cognitive disorder, clavulanic acid compound or P-glycoprotein efflux pump inhibitor, wherein the elected specie(s) is/are not adequately disclosed or supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Currently, claims 2-6 and 11 are generic.

Applicant is advised that a reply to this requirement must include identification of the single disclosed species of cognitive disorder, clavulanic acid compound or P-glycoprotein efflux pump inhibitor consistent with the instructions *supra* that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added.

An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 14, 2007

4/16/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER